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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,550	10/31/2003	Susan J. Wong	454311-2232.1	9527

20999 7590 04/19/2007  
FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK, NY 10151

EXAMINER
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HURT, SHARON L

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/699,550

Applicant(s)

WONG ET AL.

Examiner

Sharon Hurt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 69-74, 76-105, 145, 156, 162-181 and 193-202 is/are pending in the application.

4a) Of the above claim(s) 69-73 is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 74, 76-105, 145, 156, 162-181 and 193-202 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>October 16, 2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2007 has been entered.

### ***Declaration***

The Declaration under 37 U.S.C. §1.132 for Susan Wong and Pei-Yong Shi filed February 26, 2007 has been acknowledged.

### ***Response to Amendment***

The amendments to the claims filed June 22, 2006 has been entered. Claims 74, 80, 91, 99, 126-127, 145, 171-175 and 182-200 are currently amended.

The amendments to the claims filed February 26, 2007 has been entered. Claims 91, 145 and 198-202 are currently amended.

### ***Status of the Claims***

Claims 69-74, 76-105, 145, 156, 162-181 and 193-202 are pending. Claims 69-73 are withdrawn. Claims 74, 76-105, 145, 156, 162-181 and 193-202 are under examination.

### ***Response to Arguments***

### ***Priority***

The later-filed application must be an application for a patent for an invention, which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/422,755, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instant application is drawn to a method of detecting West Nile Virus (WNV) infection by detecting anti-WNV antibodies that react with the WNV NS5 protein. Provisional application 60/422,755 does not disclose a method of detecting a WNV infection by antibodies reacting to the NS5 protein. The provisional application does not describe antibodies specific for nonstructural proteins, NS5 or methods of detecting WNV as described in the instant application. Therefore benefit to provisional application 60/422,755 is denied.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 171-175, 182-190 and 192-200 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** pursuant applicant's amendments.

The rejection of claims 163, 168, 177 and 202 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** pursuant applicant's arguments.

***Claim Rejections - 35 USC § 103***

The rejection of claims 74, 76-105, 126-128, 145, 156 and 162-202 under 35 U.S.C. 103(a) as being unpatentable over Wang et al., Valdes et al., Mandy et al., Scaramozzino et al. and McDonell et al. is **maintained** for claims 74, 76-90. The rejection is withdrawn for claims 91-105, 126-128, 145, 156 and 162-202 pursuant Applicant's declaration filed February 26, 2007.

Applicant's arguments filed June 22, 2006 and February 26, 2007 have been fully considered but they are not persuasive. Applicant argues "the claims are not *prima facie* obvious over Wang, Valdes, Mandy, Scaramozzino and McDonell since there lacks any motivation or suggestion to combine the references". Applicant also argues "that neither the references themselves nor the knowledge of persons of ordinary skill in the art provide any motivation or suggestion to combine the references". In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Wang teaches a method of detecting WNV infection using a WNV E protein (page 106). Valdes teaches a method of detecting a flavivirus using the E and NS5 antigens and confirms that NS5 proteins elicit specific antibodies against a related flavivirus (page 857). Mandy teaches about microsphere suspension technology, microsphere coupling and that these techniques are applicable to biological samples (pages 714-715 and 724). Scaramozzino teaches about the detection of flavivirus by PCR with NS5 sequences and that using different NS5 locations allows for specific detection of flaviviruses including WNV from patient samples (pages 9006-9258). Scaramozzino also teaches that at the time the invention was made it was known in the art that NS5 sequences differ between related flaviviruses, which allow NS5 to be used as a diagnostic tool. McDonell teaches an immunogenic composition comprising NS proteins and immunogenic antigens that can be used to detect flavivirus infections in diagnostic assays and kits containing the assay components and instructions. It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use the NS5 protein, which elicits specific antibodies against flaviviruses including WNV, in an assay to detect WNV. The person of ordinary skill in the art would have been motivated to use NS5 because Scaramozzino teaches that this method can be used to detect WNV in samples, and reasonably would have expected success because of the teachings as set forth *supra*.

Applicant asserts that "Wang is not prior art" and "that the Declaration of March 17, 2005 is sufficient to overcome the grounds of rejection of claims as obvious" over the references. The Wang et al. reference was published in June 2002, one year prior to the effective filing date

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of the instant application. The argument about priority over the provisional application has been addressed *supra*. Therefore, Wang et al. is considered to be prior art.

Applicant argues “the invention is not obvious even if Wang is taken into consideration”. Applicant argues that “Wang would in fact teach away from the present invention thus, the combination of this reference with Valdes, Mandy, Scaramozzino and McDonell would not be proper”. Applicant argues that Valdes relates to a different flavivirus so “at best, it would have been “obvious to try” combining the references”. Applicant argues “neither Wand nor Valdes provides the requisite suggestion or desirability to be combined to reach each and every element of the invention”. Applicant also argues “that neither Wang nor Valdes, either alone or in combination, teaches nor suggests each and every element of claimed invention”. Applicant further argues that “Valdes does not correct for the deficiencies in Wang, and vice versa” and “neither Wand nor Valdes, either alone or in combination, teach a method for the detection of a WNV infection...” In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Wang and Valdes do not teach the invention alone, the instant invention is obvious over the combined references of Wang, Valdes, Mandy, Scaramozzino and McDonell.

Applicant argues that “one skilled in the art would have no motive to postulate that NS5 of WNV would have been a good diagnostic antigen since thee was not reason to presuppose that with low viremia, infected humans would have a strong immune response, i.e., generating

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antibodies against WNV NS5.” “Accordingly, the combination of this reference with Wang, Mandy, Scaramozzino and McDonell would not be proper.” In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., low viremia, strong immune response and generating antibodies) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Mandy, “although is discusses potential, it fails to demonstrate that SAT is an effective diagnostic tool for any flavivirus infection, and certainly not for WNV in particular”. Examiner disagrees because Mandy provides motivation in discussing the potential of using this technique to detect antibodies in biological samples. Applicant argues again “accordingly, the combination of this reference with Wang, Valdes, Scaramozzino and McDonell would not be proper.” Applicant argues “Scaramizzino provided no incentive or motivation to use NS5 as an antigen for antibody protection”. Applicant argues again “accordingly, the combination of this reference with Wang, Valdes, Mandy and McDonell would not be proper.” Applicant argues that McDonell only relates to “related flaiviviruses, it would not have been obvious to extend the results of McDonell to arrive at the present invention, especially in view of the unpredictability of immune responses to antigenic proteins from different viruses”. Applicant argues again “accordingly, the combination of this reference with Wang, Valdes, Mandy and Scaramozzino would not be proper.” Examiner disagrees because Valdes teaches a method of detecting a flavivirus using NS5 antigens and that NS5 proteins elicit specific



antibodies against a related flaviviruses and Scaramozzino teaches that NS5 can be used to detect WNV and related flaviviruses in samples.

Applicant argues “neither Wang, Valdes, Mandy, Scaramozzino nor McDonell either alone or in combination, teach a method for the detection of a WNV infection in a subject... In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The combination of references teach the elements of the claimed invention as set forth *supra* and in rejection of record.

The declaration filed February 26, 2007 states “this higher sensitivity is due in part to the NS5 of WNV being covalently attached via its amino terminus to the surface of polystyrene microspheres”. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., covalently attached to the surface of polystyrene microsphere) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Double Patenting***

The rejection of claims 74, 76-105, 126-128, 145, 156 and 162-202 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 93-101 (previously claims 1-9, 13-21, 24-35 and 56-57) of copending Application No. 10/839,442 is **maintained** for claims 91-105, 145, 156, 162-181 and 193-202. Although, the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method of detecting WNV infection in a subject using NS5. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

April 13, 2007



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